

Application No. 10/690,987  
September 11, 2007 Reply To Final Office Action

# REMARKS

## Summary of Office Action

Claims 29-50 are pending in this application.

Claims 29, 31, 33, 34, 45, 47, 49, and 50 have been finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg et al. U.S. Patent No. 6,807,797 (hereinafter "Forsberg") in view of Case U.S. Patent No. 4,405,317 (hereinafter "Case").

Claims 37-39, 41, 43, and 44 have been finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Case in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Dependent claims 30, 40, and 46 have been finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Case/Odell in view of Geprägs U.S. Patent No. 4,781,701 (hereinafter "Geprägs").

And claims 32, 34-36, 42, 45, and 47-50 have been finally rejected under 35 U.S.C. § 103(a) as being obvious from Tanaka et al. U.S. Patent No. 5,716,339 (hereinafter "Tanaka").

## Summary of Applicants' Reply

Applicants have proposed amending claim 45 to delete a phrase unrelated to patentability.

No new matter has been added.

Reconsideration of this application in view of the following remarks is respectfully requested.

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Showing of Good and Sufficient Reasons  
Under 37 C.F.R. § 1.116(b)(3)

Applicants request amendment of this application, even though a final rejection has been issued. The proposed amendment of claim 45, which deletes the phrase "with no significant tapering or narrowing," is unrelated to patentability over the prior art (the Examiner said the limitation "having an open mouth configuration with no significant narrowing or tapering" was given little patentable weight because the qualifier "significant" is arbitrary and has no well defined meaning in the art (*see* page 5, July 11, 2007 Final Office Action)). Therefore, this amendment should require no any additional search or consideration. Accordingly, applicants respectfully request entry of the proposed amendment.

Rejections of Claims 29, 31, 33, 34, 45, 47, 49, and 50 Under 35 U.S.C. § 103(a)

Claims 29, 31, 33, 34, 45, 47, 49, and 50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg in view of Case.

These rejections are respectfully traversed.

Independent claim 29 requires, among other things, inserting a seal structure into the chamber to divide the chamber into front and rear compartments, the chamber having no interior structures and the seal structure having a flow path formable there through.

The Examiner acknowledged that Forsberg "does not teach that the chamber has no interior structures, or the seal having a flow path formable there through" (page 3, July 11, 2007 Final Office Action).

The Examiner said that "[i]t would have been obvious to one of ordinary skill in the art ... to use the seal and barrel structure of Case with the loading method of Forsberg in

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order to provide a syringe which is loaded without mixing of the two compartments and which has an extended shelf life" (*id.*).

Applicants explained in their previous June 4, 2007 Reply to Fifth Office Action that applying the method of Forsberg to Case results in many ambiguities, because Case discloses a complex device with many parts, in particular "an outer barrel for a powder medicament [and] an inner barrel telescopically mounted in the outer barrel for [a] diluent" (abstract, lines 1-3), while Forsberg discloses a method directed to a single dual chamber barrel. Accordingly, Forsberg's method does not readily or unambiguously map to Case's device.

The Examiner responded by saying that "Case is used only to show that it is known in the art to provide reconstituting syringes which have a smooth barrel (12) and a breakable seal (34)" (pages 4-5, July 11, 2007 Final Office Action).

The Examiner also said that the "'introduction of the middle piston' step [of Forsberg's method] would simply be replaced with using the piston/breakable seal of Case" (*id.* at page 5).

Applicants respectfully submit that the Examiner is using impermissible hindsight to pick and choose specific features from Case to combine with Forsberg in order to arrive at applicants' invention.

Recall that the Examiner's reason to combine Case with Forsberg was "to provide a syringe which is loaded without mixing of the two compartments and which has an extended shelf life" (page 3, July 11, 2007 Final Office Action).

Forsberg already discloses loading a dual chamber barrel having two compartments, a front chamber 5 and a rear chamber 6 (see Forsberg FIG. 1).

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Moreover, the "piston/breakable seal of Case" comprises the following: a tubular plunger 34 sized to fit within outer barrel 12, an inner barrel 16 sized to fit within outer barrel 12 and having a reduced neck portion 30 and a radially outwardly directed bead or finish 32 to fit within the tubular opening of plunger 34, and a plug 50 sized to mount within a discharge opening 48 in finish 32 of inner barrel 16 (see Case's FIGS. 1 and 2 and column 17, lines 2-5 and 21-26).

Thus, why would a person of ordinary skill in the art replace Forsberg's much simpler piston 3 and bypass zone 4 with Case's more complex assembly of plunger 34, inner barrel 16, and plug 50?

Applicants' submit there is no obvious reason why a person of ordinary skill in the art would do so.

Nothing has been cited to indicate that those specific parts in Case's device are superior to those in Forsberg, assuming that they could even be substituted in Forsberg without a significant redesign.

Therefore, the combination of Forsberg and Case is improper and not obvious and, even if the two were combined, would not likely result in applicants' invention as defined in independent claim 29.

Claim 29 should therefore be allowable.

For at least these reasons, dependent claims 31, 33, and 34, which depend either directly or indirectly from independent claim 29, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

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Independent claim 45, which requires, among other things, inserting a seal structure into the chamber to divide the chamber into front and rear compartments, the chamber having no interior structures, should also be allowable for at least the same reasons as independent claim 29. Similarly, dependent claims 47, 49, and 50, which depend from independent claim 45, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 37-39, 41, 43, and 44 Under 35 U.S.C. § 103(a)

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Case in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

And also for at least the same reasons, independent claim 39, which requires, among other things, a seal structure having a flow path formable therein and there through, is also not obvious from the combination of Forsberg and Case.

~~Odell, purportedly, discloses methods of manufacturing drug delivery and drug~~  
container devices in clean, substantially particular-free areas and, accordingly, does not make up for the deficiencies of Forsberg and Case.

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Thus, the combination of Forsberg, Case, and Odell does not render claim 39 obvious and, therefore, claim 39 should be allowable.

For at least these reasons, dependent claims 41, 43, and 44, which depend from independent claim 39, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 37-39, 41, 43, and 44 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 30, 32, 34-36, 40, 42, and 45-50 Under 35 U.S.C. § 103(a)

Claims 30, 40, and 46 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Case/Odell in view of Geprägs. And claims 32, 34-36, 42, 45, and 47-50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Tanaka.

These rejections are respectfully traversed.

Geprägs was cited because it purportedly discloses a front syringe barrel with a tapered flow path.

Tanaka was cited because it purportedly discloses a rear chamber filled first with a substance and a front chamber filled next with a dry medication.

Accordingly, neither Geprägs nor Tanaka makes up for the deficiencies of Forsberg and Case as discussed above with respect to amended independent claims 29 and 39.

Therefore, any combination of Forsberg, Case, Odell, Geprägs, and Tanaka does not render obvious independent claim 29 or 39.

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For at least these same reasons, dependent claims 30, 32, 34-36, 40 and 42, which depend directly or indirectly from one of claims 29 or 39, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

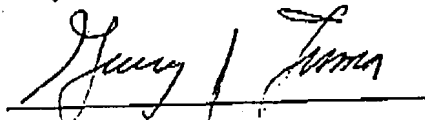
And for at least the same reasons as independent claims 29 and 39, independent claim 45 and its dependent claims 46-50, which require, among other things, a chamber having no interior structures, should also be allowable.

Accordingly, applicants respectfully request that the rejections of claims 30, 32, 34-36, 40, 42, and 45-50 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

The foregoing demonstrates that claims 29-50 are allowable. This application is therefore in condition for allowance. Reconsideration, entry of the proposed amendment, and allowance are accordingly respectfully requested.

Respectfully submitted,



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